Remarks/Arguments

Claims 16, 20 – 24, and 27 – 28 remain in this application.

Independent claim 16, as amended, discloses a method for monitoring the clinical effectiveness of the administration of a formulation comprising one or more therapeutic growth factor proteins in the treatment of coronary artery disease, the method comprising the steps of: (a) selecting a patient displaying symptoms of coronary artery disease; (b) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF-B, and mixtures thereof by inhalation therapy; (c) obtaining a sample of a biological fluid from the patient displaying symptoms of coronary artery disease; (d) performing an assay of the biological fluid to determine an amount of CPK-MB present in the fluid; (e) determining, based on monitoring the amount of CPK-MB present in the fluid, whether an additional dose of a therapeutic growth factor protein formulation is necessary; (f) depending on the results of the step e), administering one or more additional doses of a second growth factor protein formulation comprising a growth factor protein being selected from the group consisting of FGF-1, FGF-2, VEGF-B, and mixtures thereof; and (g) repeating steps c) through f) until the assayed levels of CPK-MB in the biological fluid indicates the clinical effectiveness of the administration of the pharmaceutical formulation and amelioration of the symptoms

of coronary artery disease in the patient, or until there is a contraindication to continued treatment.

Independent claim 24, as amended, recites a method for monitoring the clinical effectiveness of the administration of a potentially therapeutic pharmaceutical formulation selected from the group consisting of FGF-1, FGF-2, VEGF-B, and mixtures thereof, in the treatment of chronic coronary artery disease, the method comprising the steps of: (i) selecting a patient displaying symptoms of chronic coronary artery disease; (ii) administering at least one dose of an effective amount of a first therapeutic growth factor protein formulation comprising a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF-B, and mixtures thereof by inhalation therapy; (iii) monitoring one or more clinical indicators of chronic coronary artery disease; (iv) determining, based on monitoring the one or more clinical indicators of chronic coronary artery disease, whether an additional dose of a therapeutic growth factor protein formulation is necessary; (v) depending on the results of the step e), administering one or more additional doses of a second growth factor protein formulation comprising a growth factor protein selected from the group consisting of FGF-1, FGF-2, VEGF-B, and mixtures thereof; and repeating steps c) through f) until there is a clinical indication of amelioration of the symptoms of chronic coronary artery disease in the patient, or until there is a contraindication to continued treatment.

The Examiner's indication that the previous rejection of claims 16, 20-24, and 27-28 under 35 USC 101 as claiming the same invention as that of claims 1, 4, 5, 11,

12, 13, 14, 15, and 20 of U.S. Patent No. 6,759,386 (6 July 2004) to Franco, has been withdrawn in view of applicant's amendments is noted with appreciation.

Claims 16, 20-24, and 27-28 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 11, 12, 13, 14, 15, and 20 of U.S. Patent No. 6,759,386 (6 July 2004) to Franco in view of U.S. Patent 5,607,918 (4 March 1997).

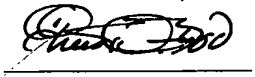
In order to expedite prosecution of this application, enclosed herewith is a Terminal Disclaimer in the form required by 37 CFR 1.321 (b). The Terminal Disclaimer includes a statement by the applicant certifying that, to the best of his knowledge and belief, title is in the applicant seeking to take action. As such, the Terminal Disclaimer is submitted to be in the proper form required by 37 CFR 1.321. In view of the same, it is submitted that present claims 16, 20-24, and 27-28 should not be subject to rejection based on obviousness-type double patenting over claims 1, 4, 5, 11, 12, 13, 14, 15, and 20 of U.S. Patent No. 6,759,386 (6 July 2004) to Franco in view of U.S. Patent 5,607,918 (4 March 1997).

Accordingly, reconsideration of the rejection of claims 16, 20 – 24, and 27 – 28 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 11, 12, 13, 14, 15, and 20 of U.S. Patent No. 6,759,386 (6 July 2004) to Franco in view of U.S. Patent 5,607,918 (4 March 1997) is respectfully requested.

Conclusion

In view of the Terminal Disclaimer submitted herewith, and the remarks set forth above, it is respectfully submitted that the present application is in allowable condition. Reconsideration of the Final Rejection, entry of this amendment and the Terminal Disclaimer submitted herewith, and allowance of present claims 16, 20 – 24, and 27 – 28 are earnestly solicited.

Respectfully submitted,
Wayne P. Franco

By: 
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